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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,983	02/28/2001	Tom Gilchrist	MUR-8564US	3635

7590 08/22/2003

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/22/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/763,983

Applicant(s)

GILCHRIST ET AL.

Examiner

Lauren Q Wells

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,8,11 and 22-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,8,11 and 22-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1617

DETAILED ACTION

Claims 1-5, 7-8, 11 and 22-28 are pending. The Amendment filed 5/27/03, Paper No. 12, amended claims 1-4, 7, 24, and added claims 27-28.

Applicant's arguments with respect to claims 1-5, 7-8, 11 and 22-28 have been considered but are moot in view of the new ground(s) of rejection.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/27/03 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "carboxymethyl-cellulose" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1617

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-8, 11, 25, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakis et al. (5,851,461) in view of Gilchrist et al. (WO 96/17595).

The instant invention is directed toward a process of producing a sterile foam.

Bakis et al. teach a method of producing polysaccharide foams. Exemplified is a solution containing sodium alginate (gelling agent) and sodium dodecyl sulfate (foaming agent), which is beaten with a mixer to form a foam. The foam is spread onto a metal tray and cross-linked with an aqueous solution containing calcium chloride (precipitant). The foam was then dried. Then the foam was spread on a mesh fabric and cross-linked with an aqueous solution of calcium chloride (2nd precipitant). The material was then dried to produce a coated pad. The coated pad was placed in an aqueous solution of HCL (organic acid) to convert the material to a soluble form. Additionally exemplified is washing the foam in deionized water. A drying step is exemplified, wherein the foam is hot air convention dried at 80 C. The reference lacks a sterilization step and lacks teaching the MW of sodium alginate. See Col. 3, line 13-Col. 4, line 65; Col. 8, lines 15-59; Col. 10, line 20-Col. 11, line 34.

Gilchrist et al. teach foamable formulations and foams. Alginate is taught as a foamable carrier having a MW from 10,000-200,000kDa. A method of making the foam is taught, wherein the foams are sterilized via gamma radiation. See pg. 5, line 15-pg. 6, line 12; pg. 8, line 4-pg. 9, line 16; pg. 10, lines 4-17; pg. 11, lines 7-12; pg. 12, lines 7-31.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the foams of Bakis et al. as being sterilized by gamma radiation, as taught by

Art Unit: 1617

Gilchrist et al., because of the expectation of achieving a product that is sterile and can thus be safely, medically applied.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the alginate of Bakis as having the MW taught by Gilchrist et al. because of the expectation of achieving a polysaccharide with a MW that is suitable for forming a stable, medically useful foam.

While the amount of the organic acid to the gelling agent is not specifically disclosed, the Examiner respectfully points out that it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

While the reference does not teach immersing the foam in a bath of precipitate, it does teach combining the foam with the precipitate. Thus, whether this combination occurs in a bath or other medium is not relevant.

Regarding claim 2, it is respectfully pointed out that the gelling agent and the precipitant must have ultimately been packaged separately, as Bakis teaches them as separate ingredients that are combined. Thus, they must ultimately come from separate packages. Furthermore, it is respectfully pointed out that the instant independent claim is directed to a process of making a sterile foam. Thus, the way in which the ingredients are packaged is irrelevant.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bakis et al. in view of Gilchrist et al. as applied to claims 1-5, 7-8, 11, 25, 26 and 27 above, and further in view of Kobayashi et al. (5,641,450).

Bakis et al. and Gilchrist et al. are applied as discussed above. The references lack a glycerine wash.

Kobayashi et al. teach a process of making a module including a polysulphonic hollow fiber membrane. A water/glycerine wash is taught as a means preventing drying and hence deterioration of a product prior to being cut to a predetermined length. See Col. 4, lines 3-11.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add glycerine to the water wash of the combined references because of the expectation of achieving a foam product that does not deteriorate upon cutting.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bakis et al. in view of Gilchrist et al. as applied to claims 1-5, 7-8, 11, 25, 26 and 27 above, and further in view of Kehr et al. (4,201,846).

Bakis et al. and Gilchrist et al. are applied as discussed above. The references lack oven-drying.

Kehr et al. teach a dimensionally stable polyurethane foam. The foams were microwave dried, vacuum oven dried, and then air dried for 2 days. See Col. 9, line 20-Col. 10, line 12.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add oven drying, as taught by Kehr et al., to the drying step of the combined references because of the expectation of achieving enhanced moisture evaporation and hence, stability of the foam. Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the oven drying taught by Kehr et al. for the convention drying of the combined references because of the expectation of achieving similarly dried foams.

Claims 24 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakis et al. in view of Gilchrist et al. as applied to claims 1-5, 7-8, 11, 25, 26 and 27 above, and further in view of Clare et al. (4,693,728).

Bakis et al. and Gilchrist et al. are applied as discussed above. The references lack calcium citrate.

Clare et al. teach hydrocolloid blend for controlled release of calcium ions. The reference teaches that the introduction of divalent ions into soluble alginate solutions rapidly causes gelation through the formation of mixed alginate salts. Where it is desirable to control the speed of this gelation, various methods have been proposed, such as combining calcium citrate with soluble alginated to produce calcium ions that are released over time. See Col. 1, lines 5-42.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute calcium citrate for the calcium chloride of the combined references because calcium citrate and calcium chloride are equivalent in their effect of slowly releasing metal ions from foams, and because of the expectation of achieving a method wherein lower concentrations of alginate are used to generate a given viscosity.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for

Application/Control Number: 09/763,983

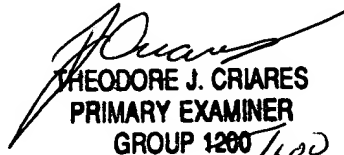
Page 7

Art Unit: 1617

the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
July 15, 2003


THEODORE J. CRIARES
PRIMARY EXAMINER
GROUP 1200/600